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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,416	12/20/2001	Kenneth Joseph Leto	BB1057 US CNT	2578

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,416

Applicant(s)

Leto et al

Examiner

Fox

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 9, 35 + 36 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 9, 35 + 36 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The application should be reviewed for errors. Errors appear, for example, in claim 35, where "Seec" should be replaced with --Seed--.

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

See, e.g., page 11 of the specification, lines 24-26; page 18, lines 4, 6 and 9-12; page 24, lines 20 and 22; page 39, line 37; page 40, lines 9-11.

Alternatively, a Substitute Specification excluding the claims, and in compliance with 37 CFR 1.125(a), may be submitted.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claims 2-8 and 10-34 have been cancelled, as instructed on page 2, top line of the preliminary amendment of 20 December 2001. Claim 1 has also been canceled, as instructed on

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page 2, second paragraph of the "Remarks" section of that amendment. Claims 9 and 35-36 are pending.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specifically, the specification should be amended to insert the following paragraph on page 1, after the Title:

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Serial No. 09/303,917 filed 3 May 1999, now abandoned, which is a divisional of application Serial No. 08/693,079 filed 13 August 1996, now U.S. Patent 6,248,939, which is a 371 of PCT/US95/02076 filed 15 February 1995, which is a continuation-in-part of application Serial No. 08/196,622 filed 15 February 1994, now abandoned.--

Note that the continuity data provided on page 2 of the preliminary amendment of 20 December 2001, under the first paragraph of the "Remarks" section, is incorrect regarding the Serial No. of the patented application, the 371 status of that application, and the continuation-in-part status of the PCT.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9 and 35-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,248,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to utilize the progeny of a selfing of high oleic inbred AEC272OL as claimed in the patent to obtain the inbred AEC272OL and progeny thereof as claimed in the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite in its recitation in line 1 of "plants and plant parts" which employs improper Markush terminology. Replacement of "and" in line 1 with --or-- would obviate this rejection. See MPEP 2173.05(h).

Claim 36 is also indefinite in its recitation of "plant...produced from any pedigree derived from the corn line of claim 9". A pedigree is a breeding record, rather than an actual plant, so that it is confusing to designate a living plant as being derived from an inanimate breeding record.

Claim 36 is also indefinite in its recitation of "high oleic characteristics of high oleic corn inbred line designated AEC272OL", as it is unclear what is intended by "high oleic characteristics". This particular term is not defined in the specification, and the discussion in the specification regarding preferred levels of oleic acid content is contradictory. "Higher than normal" oleic acid level is defined as 35-40% in the sentence bridging pages 27 and 28 of the specification, while "high oleic" is defined on page 15 of the specification, lines 12-16 as "not less than about 50%". A "preferred" "high-oil, high oleic" parent is defined on page 10 of the specification, lines 25-31 as one capable of producing kernels having not less than 55% oleic acid. However, this level appears to be associated with a plant which is both high-oil and high-oleic acid, in contrast to the instant claim. In addition, it is unclear whether single or multiple characteristics are intended.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to any corn progeny plant somehow “derived from” the high oleic acid mutant AEC272OL, i.e. wherein AEC272OL was a single parent of the progeny when crossed to an undefined second parent at some point in its ancestry, at an undefined number of prior generations, which plant has undefined “high oleic characteristics”. In contrast, the specification only demonstrates the obtention of the deposited AEC272OL inbred line, and the obtention of progeny exhibiting not less than 55% oleic acid only when AEC272OL is crossed with the second mutated high-oleic line B73OL (see pages 20-27, Tables 1-3). When five other parents were crossed with AEC272OL, four of the five other parents produced progeny corn plants which produced seed with oleic acid contents ranging from 18% to 48% (see, e.g., pages 40-41, Table 6), wherein normal corn varieties are characterized as having an oleic acid content of approximately 25% (see, e.g., page 1 of the specification, line 16).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise

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definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to selfed AEC272OL progeny or progeny of the cross between AEC272OL and B73OL, which progeny produce corn kernels with oil having not less than about 55% oleic acid, does not reasonably provide enablement for claims broadly drawn to any corn plant of any unspecified parentage which possesses “high oleic characteristics”. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claim is broadly drawn to any corn progeny plant somehow “derived from” the high oleic acid mutant AEC272OL, i.e. wherein AEC272OL was a single parent of the progeny when crossed to an undefined second parent at some point in its ancestry, at an undefined number of prior generations, which plant has undefined “high oleic characteristics”. In contrast, the specification only demonstrates the obtention of the deposited AEC272OL inbred line, and the obtention of progeny exhibiting not less than 55% oleic acid only when AEC272OL is crossed with the second mutated high-oleic line B73OL (see pages 20-27, Tables 1-3). When five other parents were crossed with AEC272OL, four of the five other parents produced progeny corn plants which produced seed with oleic acid contents ranging from 18% to 48% (see, e.g., pages 40-41, Table 6), wherein normal corn varieties are characterized as having an oleic acid content of approximately 25% (see, e.g., page 1 of the specification, line 16).

Breeding corn for high oleic acid content is unpredictable, as evidenced by the failure of Applicants to maintain their 55% oleic acid content following outcrossing to a majority of non-AEC272OL parents, wherein most outcrosses and/or backcrossing to a non-AEC272OL parent resulted in lower oleic acid levels which often approached or went below those of “normal” corn varieties, as stated above. In addition, the inheritance of the high oleic acid trait in corn is not well understood, with conflicting reports of single gene control, multiple loci, dominant as well as recessive effects, and partial dominance (see, e.g., page 5 of the specification, lines 14-37). Even

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Applicants admit that additive effects were observed, which precluded simple Mendelian ratios, and which would hamper simple, predictable transmission of the high oleic acid trait into other varieties (see, e.g., page 40 of the specification, lines 7-14).

Inheritance and transmission of high oleic acid content appears to be highly dependent on the genotype of the particular parent(s) used. Alrefai et al report that oleic acid content in corn produced by progeny of a particular cross was quantitatively inherited, and was governed by at least twelve loci in eight regions of the corn genome, with half the loci showing additive effects and half showing dominance effects (see, e.g., page 898, paragraph bridging the columns). Thus, the effects of a multitude of non-exemplified parental lines on the ability of the AEC272OL parent to transmit its high oleic acid trait is unclear. Furthermore, Alrefai et al also teach that oleic acid content is highly environmentally dependent (see, e.g., page 898, Table 3, "18:1" column).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to evaluate and obtain a multitude of non-exemplified progeny, from a multitude of non-exemplified crosses with a multitude of non-exemplified parents over a multitude of generations, for high oleic acid content.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 36 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Misevic et al.

The claim is broadly drawn to any progeny corn plant which was somehow derived from the cross of AEC272OL with another unspecified parent, at some point in its pedigree, followed by an unspecified number of outcrosses to other (or the same) non-AEC272OL parent for an unspecified number of generations, wherein the progeny has "high oleic characteristics", wherein this term is undefined, but wherein "high oleic content" is variously defined as 35%, 40%, or at least about 50%, as stated above.

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Misevic et al teach individual corn plants with oleic acid contents in their seed of 43.35% (see, e.g., page 287, Table 3). The prior art high oleic acid corn plants differ from the claimed high oleic acid corn plant only in its method of production, namely the use of AEC272OL at some point in its pedigree. However, the process of making the prior art corn plant would not distinguish the plant itself from the claimed corn plant, particularly in view of the loss of AEC272OL-derived genetic material in each generation of outcrossing to a non-AEC272OL parent, and as the high oleic acid trait or its genetic components are not unique to AEC272OL. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim 36 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wright.

Wright teaches a high oleic corn plant which produces seeds having 55.2% oleic acid (see, e.g., page 86, Table 1). The prior art high oleic acid corn plants differ from the claimed high oleic acid corn plant only in its method of production, namely the use of AEC272OL at some point in its pedigree. However, the process of making the prior art corn plant would not distinguish the plant itself from the claimed corn plant, particularly in view of the loss of AEC272OL-derived genetic material in each generation of outcrossing to a non-AEC272OL parent, and as high oleic acid is not unique to AEC272OL. See *In re Thorpe* cited above.

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Claims 9 and 35 are deemed free of the prior art, given the failure of the prior art to teach or suggest the exemplified and deposited high oleic acid inbred, as stated in allowed parent application Serial No. 08/693,079, now U.S. Patent 6,248,939.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 23, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.